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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,504	11/19/2003	Gordon H. Epstein	021872-001010US	8230
20350 7590 10/30/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER RYCKMAN, MELISSA K	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 10/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/718,504

Applicant(s)

EPSTEIN ET AL.

Examiner

Melissa Ryckman

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on received on 7/19/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This office action is in response to claims filed 7/19/07.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Marino et al. (US 6913614). Marino teaches an expansible device (10) for use in a body lumen or tract, the device comprising: a tubular member (16) having a proximal end and a distal

end; a first expansible member (24) disposed on the distal end of the tubular member, the first expansible member (24) having a contracted configuration (Fig. 5) and an expanded configuration (Fig. 1), wherein the first expansible member comprises a wire that can be shifted between an elongate contracted configuration and a helical expanded configuration (26 forms a helix when viewed along the longitudinal axis along 14); a first deformable membrane (32) at least partially disposed over the first expansible member in the expanded configuration; a second expansible member (22) disposed proximal the first expansible member on a distal end of the tubular member (16), the second expansible member having a contracted configuration and an expanded configuration (fig. 5).

Claims 19, 20, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Latson et al. (US 5861003).

Regarding Claim 19, Latson teaches an expansible device for use in a body lumen or tract, the device comprising: a tubular member (7) having a proximal end and a distal end; a first expansible member (distal end of frame 9) disposed on the distal end of the tubular member, the first expansible member having a contracted configuration (fig. 3) and an expanded configuration (fig. 6), wherein the first expansible member comprises a wire (9) that can be shifted between an elongate contracted configuration and a helical expanded configuration (Fig. 6 is helix, Fig. 5 is contracted); a first deformable membrane (6) at least partially disposed over the first expansible member in the expanded configuration; a second expansible member (proximal end of frame 9) disposed proximal the first expansible member on a distal end of the tubular

member, the second expansible member having a contracted configuration (fig. 3) and an expanded configuration (fig. 6).

Regarding Claim 20, Latson teaches the device of claim 19, wherein the second expansible member has a cylindrical shape in the expanded configuration (fig. 6).

Regarding Claim 22, Latson teaches the device of claim 20, wherein the second expansible member comprises a coil or spring of wire (9).

Regarding Claim 24, Latson teaches the device of claim 22, further comprising a second deformable membrane (5) at least partially disposed over the second expansible member in the expanded configuration (fig. 6).

Regarding Claim 25, Latson teaches the device of claim 24, further comprising ribs on a surface of the second deformable membrane (col. 4, ll. 36,37).

Claims 19, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Khaikhahan et al. (US 2002/0111647).

Regarding Claim 19, Khaikhahan teaches an expansible device for use in a body lumen or tract, the device comprising: a tubular member (16) having a proximal end and a distal end; a first expansible member (11) disposed on the distal end of the tubular member, the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible member (11) comprises a wire (Fig. 7, distal portion of 190 is the wire) that can be shifted between an elongate contracted configuration and a helical expanded configuration (Fig 7, 218 forms a helix); a first deformable membrane (15) at least partially disposed over the first expansible

member in the expanded configuration (fig. 1); a second expansible member (194) disposed proximal the first expansible member on a distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration.

Regarding Claim 26 Khairkhahan teaches the device of claim 19, wherein the second expansible member (194) has a length in a range from about 0.1 inch to about 2.0 inches (paragraph 54).

Regarding Claim 27, Khairkhahan teaches the device of claim 19, wherein the first deformable membrane comprises a spherical shape when the first expansible member is in the expanded configuration (fig. 1).

Regarding Claim 28, Khairkhahan teaches a reference stop (distal portion of 195 is a reference stop) disposed between the first deformable membrane (15) and the distal end of the tubular member (16).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 20, 21, 29, 30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al. (US 6071300) in view of Kensey (US 5061274)

Brenneman teaches a method of sealing a puncture site comprising the following: providing an expansible device having a tubular member (20), a first expansible member (50) disposed on a distal end of the tubular member (20) wherein the first expansible member comprises a wire (82) that can be shifted between an elongate contracted configuration and a helical expanded configuration (having the form of a spiral includes a curve formed about the axis, a partial helix is shown in Fig. 4A); and a second expansible member (42) disposed proximal the first expansible member on the distal end of the tubular member; inserting the expansible device in the puncture site (fig. 1a); deploying the first expansible member to an expanded configuration comprising a spherical shape (fig. 1b); deploying the second expansible member to an expanded configuration comprising a cylindrical shape (fig. 7).

wherein the first and second expansible members (50,42) are deployed sequentially (figs. 1a-1c, fig. 1).

wherein the first expansible member is deployed against a blood vessel wall (fig. 1).

wherein the second expansible member is deployed against a tissue tract (fig. 1).

wherein deploying the second expansible member comprises inflating the second expansible (42) member with a predetermined volume of air (fig. 1c to fig. 5).

Brenneman fails to teach wherein the first expansible member comprises a first deformable membrane at least partially disposed over the first expansible member in an

expanded configuration. Kensey teaches a method for sealing a puncture site, wherein the expansible member (20) is covered with a non-thrombogenic waxy membrane in order to minimize the risk of thrombosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brenneman with a membrane on the first expansible member as taught by Kensey in order to minimize the risk of thrombosis.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brenneman and Kensey as applied to claim 29 above, and further as a matter of design choice. The combination of Brenneman and Kensey teaches all limitations of dependent claim 29, and further teaches wherein wherein the first and second expansible members are deployed sequentially, but fails to teach wherein the first and second expansible members are deployed simultaneously. It would have been an obvious matter of design choice to modify the method of Brennemen by simultaneously deploying the first and second expansible members, since the combination of Brenneman and Kensey is capable of performing that function, and in paragraph 79 of the present application, applicant asserts that it is preferable to deploy the first and second members sequentially, and it appears that the method of the combination of Brenneman and Kensey performs the task of sealing a puncture equally well as that of the present application.



Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Latson as applied to claim 20 above, further in view of Khairkhahan et al, and further as a matter of design choice.

Latson teaches all limitations of preceding dependent claims 19, 20 and 22 as previously described, but fails to disclose the diameter of the coil wire. Khairkhahan teaches a device for occluding an opening, wherein the second expansible member is of a diameter .19 inches. It would have been an obvious matter of design choice to disclose the diameter of the coil and wire as being within the disclosed range since it appears that the device of Latson performs the task of closing a hole in tissue equally well as that of the disclosed application, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed 7/19/06 have been fully considered but they are not persuasive. The applicant generally argues the new amendments overcome the prior art of record, however the examiner respectfully disagrees with the applicant as stated in the above rejection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/718,504

Page 10

Art Unit: 3773

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

A handwritten signature in black ink, appearing to read "MJ Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER